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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,856	12/31/2001	Dilip Wagle	361331-507	4036
30623	7590	11/22/2005	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			DELACROIX MUIRHEI, CYBILLE	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No.	Applicant(s)	
	10/036,856	WAGLE ET AL.	
	Examiner	Art Unit	
	Cybillie Delacroix-Muirheid	1614	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 07 October 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1, 2 and 4-7.  
Claim(s) withdrawn from consideration: 3.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

  
**CHRISTOPHER S. F. LOW**  
 SUPERVISORY PATENT EXAMINER  
 TECHNOLOGY CENTER 1603

Continuation of 11. does NOT place the application in condition for allowance because: of reasons given previously in the office actions mailed June 6, 2005 and Nov. 15, 2004. Applicant's remarks and declaration have been considered but are not found to be persuasive.

Applicant states that high intraocular pressure is a major risk factor for glaucoma. Glaucoma is an eye disorder that causes progressive and irreversible optic nerve damage and vision loss. There are several risk factors for developing glaucoma, one of them being diabetes. Glaucoma treatment entails decreasing aqueous humor production, increasing fluid drainage or combination of the two, thereby decreasing intraocular pressure.

On the other hand, diabetic retinopathy is a disorder of the retinal blood vessels resulting from diabetes. Everyone who has diabetes is at risk for developing diabetic retinopathy, but not all diabetics do develop it. Although diabetes and diabetic retinopathy are risk factors for increased intraocular pressure and glaucoma, not all diabetics or people suffering from diabetic retinopathy develop increased intraocular pressure. Thus, applicant argues that one of ordinary skill in the art would readily recognize that the etiology, symptoms and treatment of glaucoma/increased intraocular pressure is quite different from that of diabetic retinopathy and would further recognize that while diabetics are twice as likely to develop glaucoma as compared to the general population, glaucoma is not a natural consequence that necessarily flows from diabetes or diabetic retinopathy.

Said arguments have been considered but are not found to be persuasive.

Initially, the examiner notes that applicant's arguments pertaining to the treatment of glaucoma are not commensurate in scope with the claims. Secondly, while paragraph 8 of the declaration asserts that glaucoma is not a natural consequence that necessarily flows from diabetes, applicant's specification states that ophthalmologic disorders in diabetes include opacification and glaucoma and that the incidence of glaucoma is significant in diabetic populations. (page 1, lines 18-21), Therefore, since the specification states that the method involves treating mammals with glaucoma and reduced accommodation caused by certain diseases such as diabetes (page 3, lines 4-7) and the method disclosed by Wagle involve treating diabetes or adverse sequelae of diabetes, the examiner respectfully maintains that a decrease in intraocular pressure or an improvement in ocular accommodation would be an inherent characteristic of the disclosed method.

Finally, concerning the submission of the declaration after final rejection, the examiner respectfully submits that it is not clear from the remarks in the declaration or applicant's remarks as to why the declaration could not have been presented earlier.